

U.S. Patent Application Serial No. 10/594,449
Amendment filed April 25, 2008
Reply to OA dated October 29, 2007

REMARKS

Claims 1-12 are pending in this application. Claims 1, 2, 3, 4, 6 and 7 are amended herein. Upon entry of this amendment, claims 1-12 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

Claims 1-4, 6 and 7 are objected to because of informalities. (Office action p. 2)

The Examiner requests that the parenthetical wording "(excluding infectious laryngotracheitis virus)" should be replaced with a clear "wherein" or similar clause. The claims have been amended to eliminate the parenthetical expressions.

With regard to claim 2, the Examiner requests that "a DNA" be changed to --the DNA--. However, since a plurality different DNA's can encode the amino acid sequence set forth in SEQ ID NO: 4, the indefinite article "a" is appropriate, and claim 2 is not amended in this regard. That is, this recitation is to a DNA sequence within the recombinant herpesvirus.

Claims 4 and 7 have been amended as suggested by the Examiner.

Claims 1-12 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. (Office action p. 2)

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Reconsideration of the rejection is respectfully requested in view of the amendments to the claims.

The Examiner states that "the claims are interpreted as being drawn to a genus of recombinant viruses ..." (page 3, lines 11-12) and that "the only factor present in the claims is SEQ ID NO: 4. There is no disclosure of any particular portion of the structure that must be conserved or deleted, added or substituted" (page 4, lines 2-4). The Examiner refers specifically to the disclosure at page 5 of the specification that "[o]ne or a plurality of amino acids of the amino acid sequence set forth in SEQ ID NO: 4 may be deleted, added or substituted."

That is, the Examiner is stating that the sequence recited in claim 1, in which "one or a plurality of amino acids have been deleted, added or substituted in said polypeptide," or the similar recitation in claim 2, is too broad. In response, claims 1 and 2 have been amended to recite: "in which from one to seven amino acids have been deleted, added or substituted." That is, "a plurality" is now limited to a maximum of seven.

Support for this amendment may be found in the specification, on page 5, lines 25 to 30, which reads: "The gB gene is not specifically limited, and any gene encoding the gB protein derived from ILTV may be used, and there can be mentioned, for example, the gB gene (GeneBank ACC. No. X65093) derived from the highly toxic field isolate 632 strain and the gB gene (GeneBank ACC. No. M64927) derived from the SA2 strain".

Applicant has provided, below, a sequence alignment showing the differences between these explicitly disclosed sequences. As can be seen from the enclosed sequence alignment, the sequence

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of the present invention (marked as “zeon”) and the sequence of the 632 strain are different by 2 amino acid residues, and the sequence of the present invention (marked as “zeon”) and the sequence of the SA2 strain are different by 7 amino acid residues. That is, the specification provides specific written description for sequences differing by 2 and by 7 amino acids, supporting the amended recitation that “from one to seven amino acids have been deleted, added, or substituted.”

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SA	Sequence	MTTNYWDA LFFNLYSK EDDDKKPP DDDAKKAA EKKKQITAE EKKKKKKK
zeon	Sequence	-----
		730 740 750 760 770 780
632	Sequence	KKKKKKKK SSSSSSSS EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK
SA	Sequence	KKKKKKKK SSSSSSSS EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK
zeon	Sequence	-----
		790 800 810 820 830 840
632	Sequence	KKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK
SA	Sequence	KKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK
zeon	Sequence	-----
		850 860 870 880 890 900
632	Sequence	KKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK
SA	Sequence	KKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK EKKKKKKK
zeon	Sequence	-----

Claims 1-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office action p. 5)

The rejection is overcome by the amendments to the claims.

The Examiner refers to the recitation in claim 1 of "a DNA that encodes a polypeptide comprising 429 amino acids at the amino terminal end of a protein encoded by the gB gene of infectious laryngotracheitis virus or a polypeptide in which one or a plurality of amino acids have been deleted, added, or substituted in said polypeptide." The rejection here appears to be directed only to the grammar of this recitation, in particular, confusion over the recitation of "a polypeptide" and "said polypeptide." The claims have been amended to clarify this recitation.

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The Examiner also appears to be uncertain with regard to the relationship of SEQ ID NO: 4 and the polypeptide in claim 1. However, SEQ ID NO: 4 is a 40-amino acid sequence and is not the 429 amino acid sequence. Claim 1 has therefore been amended to refer specifically to SEQ ID NO: 2, instead of the "polypeptide comprising 429 amino acids."

Claims 1 and 4-10 are rejected under 35 U.S.C. §102(b) as being anticipated by Keeler et al. (U.S. Patent No. 5,443,831). (Office action p. 5)

Reconsideration of the rejection is respectfully requested in view of the amendments to the claims. In particular, claim 1 has been amended to recite that the recombinant herpesvirus "does not encode any other portion of the gB gene of infectious laryngotracheitis virus" than the recited polypeptide (or modified polypeptide) of SEQ ID NO: 2. This recitation is fully supported by the general disclosure of the specification, in which the 429-amino sequence of SEQ ID NO: 2 is used. For example, on page 3, line 24 and ff., the specification indicates that attempts to prepare a recombinant herpesvirus in which a promoter was ligated upstream to full-length ILTV were unsuccessful, and that the gB gene was therefore shortened "**to a predetermined length**," i.e., that encoding the 429-amino acid sequence of SEQ ID NO: 2.

The Examiner cites Keeler et al. for disclosing a recombinant vaccine comprising the ILTV gB protein inserted in non-essential sequences of a viral vector, and that this viral vector can be a herpesvirus.

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Keeler et al. discloses the isolation, sequencing and use of a viral glycoprotein gene comprising the nucleic acid sequence encoding an envelope glycoprotein of ILV, which is homologous to the gB protein of Herpes Simplex Virus Type I. The Sequence Listing includes one sequence, a 3065-bp DNA sequence encoding 874 amino acids.

However, Keeler does **not** disclose the specific 429-amino acid fragment of SEQ ID NO: 2, nor any fragment within 7 amino acid modifications of SEQ ID NO: 2.

The amended wording of claim 1 excludes the ILTV gB gene of Keeler, which would encode the 429-amino acid polypeptide **plus additional portions** of the gB gene of infectious laryngotracheitis virus.

Keeler does not suggest or motivate use of a portion of the ILTV gB gene encoding only the particular SEQ ID NO: 2 fragment of the ILTV gB protein, as recited in claim 1.

The claims, as amended, are therefore not anticipated by, and are not obvious over, Keeler '831.

Claims 1 and 4-10 are rejected under 35 U.S.C. §102(b) as being anticipated by Audonnet et al. (U.S. Patent No. 5,980,906). (Office action p. 6)

Reconsideration of the rejection is respectfully requested in view of the amendments to the claims. As noted above, claim 1 has been amended to recite that the recombinant herpesvirus "does

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not encode any other portion of the gB gene of infectious laryngotracheitis virus" than the recited polypeptide (or modified polypeptide) of SEQ ID NO: 2.

The Examiner cites Audonnet as disclosing "a vaccine comprising antigens (e.g., the ILTV gB protein) inserted into an avian herpes virus."

Audonnet discloses live recombinant avian vaccine comprising an avian herpesvirus comprising at least one nucleotide sequence coding for and expressing an antigenic polypeptide of an avian pathogenic agent (abstract). The Examiner states that ILTV gB protein can be the antigen. This apparently refers to the disclosure at column 3, lines 31-32, of the reference. However, the reference lists many possible antigens, and for ILTV also lists gC, gD and gH+gL, and in particular, **does not discuss any particular fragments of ILTV gB.**

Therefore, there is no disclosure of or suggestion for the limitation of amended claim 1, and the present claims are not anticipated by, and not obvious over, Audonnet '906.

Claims 1 and 4-10 are rejected under 35 U.S.C. §102(b) as being anticipated by Cochran et al. (U.S. Patent No. 6,183,753). (Office action p. 6)

Reconsideration of the rejection is respectfully requested in view of the amendments to the claims. As noted above, claim 1 has been amended to recite that the recombinant herpesvirus "does not encode any other portion of the gB gene of infectious laryngotracheitis virus" than the recited polypeptide (or modified polypeptide) of SEQ ID NO: 2.

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The Examiner cites Cochran as disclosing a vaccine comprising antigens (e.g., the ILTV gB protein) inserted into a chimera comprising HVT and MDV. The Examiner cites column 9, lines 10-15 and 29-33, in particular, as disclosing ILTV gB.

Cochran mentions DNA encoding an antigenic polypeptide, which can be any of a long list of polypeptides (see column 9, lines 16-26), with ILTV gB is listed as one of three "preferred" polypeptides in one embodiment. However, there is no specific disclosure of use of a shortened ILTV gB, in particular, the SEQ ID NO: 2 polypeptide. Accordingly, the pending claims are not anticipated by, and not obvious over, Cochran '753.

Claims 1 and 4-10 are rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1-10, 13 and 24 of U.S. Patent No. 6,632,664 in view of Tong et al. (Avian Pathology, 2001, 30:142-148). (Office action p. 7)

Reconsideration of the rejection is respectfully requested in view of the amendments to the claims. As noted above, claim 1 has been amended to recite that the recombinant herpesvirus "does not encode any other portion of the gB gene of infectious laryngotracheitis virus" than the recited polypeptide (or modified polypeptide) of SEQ ID NO: 2.

The Examiner states that "the '664 patent does not specifically teach the use of the gB gene from ILTV as the foreign gene; however, it would have been obvious ... to use the gB gene of ILTV"

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Claim 1 of the '664 patent recites a recombinant herpesvirus with "a foreign gene" inserted into the virus. ILTV is recited in claims 6 and 10; however, the gB of ILTV is not specifically recited in the claims and does not appear to be mentioned in the '664 patent. Tong et al. is cited for teaching that "the gB protein of ILTV is a prime candidate for avian viruses and that a subunit vaccine made of a 205kDa complex containing the gB of ILT protected chickens ..."

Tong discloses construction of rFPV-ILTVgB on page 144, first column, last paragraph, and this is based on the published sequence encoding gB of ILTV SA₂, apparently using "the **complete gB gene**" (emphasis added). There is **no disclosure of use of a shortened version of the gB protein**, and no clear suggestion to use a shortened version.

Accordingly, the present claims, as amended, are not obvious under the doctrine of obviousness-type double patenting over claims 1-10, 13 and 24 of U.S. Patent No. 6,632,664 in view of Tong et al. (Avian Pathology, 2001, 30:142-148).

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

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In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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PATENT & TRADEMARK OFFICE

Enclosure: Petition for Extension of Time

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